IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED: 06.08.2007

CORAM

THE HON'BLE MR.JUSTICE R.BALASUBRAMANIAN
&
THE HON'BLE MRS.JUSTICE PRABHA SRIDEVAN

W.P.NOS.24759 OF 2006 & 24760 OF 2006

Novartis AG
Schwarzwaldalle 215
4058 Basel and Lichstrasse 35
4002 Basel, Switzerland represented
by it's Power of Attorney
Ranjna Mehta Dutt ..Petitioner in
W.P.24759/06

Novartis India Ltd.
Sandoz House
Dr.Annie Besant Road
Worli, Mumbai - 400 018
represented by it's Power of
Attorney Saibal Mukherjee ..Petitioner in
W.P.24760/06

Vs.

1.Union of India
through the Secretary
Department of Industry
Ministry of Industry and Commerce
Udyog Bhavan, New Delhi
2.The Controller General of Patents & Designs
through the Patent Office
Intellectual Property Rights Building
G.S.T.Road, Guindy, Chennai - 600 032
3.Natco Pharma Ltd.
"Natco House"
Road No.2, Banjara Hills
Hyderabad - 500 033
4.M/s.Cipla Ltd., India
289, Bellasis Road
Opp.Hotel Sahil, Mumbai Central (E)
Mumbai - 400 008
5.M/s.Hetro Drugs Ltd., India
H No.8-3-168/7/1, Erragada
Hyderabad - 500 018
6.M/s.Cancer Patient Aid Association, India
No.5, Malhotra House, Opp.G.P.O.
Mumbai - 400 001

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7.M/s.Ranbaxy Laboratories Ltd., India
12th Floor, Deviks Tower
No.6, Nehru Place, New Delhi - 110 019
8.Indian Pharmaceutical Alliance
represented by it's Secretary General
C/o.Vision Consulting Group
No.201, Darvesh Chambers
Khar, Mumbai - 400 052
9.M/s.Sun Pharmaceutical Industries Limited
Acme Plaza, Opp.Sangam Cinema
Andheri - Kurla Road
Andheri (E), Mumbai - 400 059

(R8 and R9 impleaded as per order dated 29.01.2007 passed in M.P.Nos.3 & 5/06 in W.P.No.24759/2006) ..Respondents in W.P.24759/06

1.Union of India
through the Secretary
Department of Industry
Ministry of Industry and Commerce
Udyog Bhavan, New Delhi
2.The Controller General of Patents & Designs
through the Patent Office
Intellectual Property Rights Building
G.S.T.Road, Guindy, Chennai - 600 032
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7.M/s.Ranbaxy Laboratories Ltd., India
12th Floor, Deviks Tower
No.6, Nehru Place, New Delhi - 110 019 ..Respondents in W.P.24760/06

Prayer in W.P.No.24759/2006: Writ petition under Article 226 of the Constitution of India praying to issue a writ of declaration declaring that section 3(d) of the Patents Act, 1970 as substituted by the Patents (Amendment) Act, 2005 (Act 15/2005) is non-complaint with the TRIPS Agreement and / or is unconstitutional being vague, arbitrary and violative of Article 14 of the Constitution of India and consequentially

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to direct the second respondent to allow the Patent Application bearing No.1602/MAS/98 filed by the petitioner.

Prayer in W.P.No.24760/2006: Writ petition under Article 226 of the Constitution of India praying to issue a writ of declaration declaring that section 3(d) of the Patents Act, 1970 as substituted by the Patents (Amendment) Act, 2005 (Act 15/2005) is non-complaint with the TRIPS Agreement and / or is unconstitutional being vague, arbitrary and violative of Article 14 of the Constitution of India.

For Petitioner in both W.Ps: Mr.Habuibulla Badsha, SC,
: Mr.Soli Sorabjee, SC and
: Mr.Shanthi Bhushan, SC for
: Mr.C.Daniel
For R1 and R2 : Mr.V.T.Gopalan, SC for
: Mr.P.Wilson, Asst.Sol.General
For Respondent No.3 : Mr.P.S.Raman, AAG for
: Mr.A.A.Mohan
For R4, R8 and R9 : Mr.P.Aravind Datar, SC
: Mr.R.Thiagarajan, SC &
:Mr.K.M.Vijayan, SC for
: Mr.A.Ramesh Kumar
For Respondent No.5 & 7 : Mr.Lakshmi Kumaran
For Respondent No.6 : Mr.Anand Grover for
: Ms.R.Vaigai

COMMON ORDER

(Order of the court was delivered by Justice R.Balasubramanian)

The writ petitioner in both the writ petitions is one and the same. In the first writ petition, Novartis - a foreign company represented by it's Indian Power of Attorney holder, is the writ petitioner. In the second writ petition, Novartis India represented by it's power agent is the writ petitioner. The respondents in both the writ petitions are one and the same. The prayer in both the writ petitions is one and the same namely, for a declaration that section 3(d) of the Patents Act, 1970, amended by Patents (Amendment) Act 15/2005, is unconstitutional. However, in the first writ petition there was an additional prayer in addition to the relief asked for. The additional prayer was to direct the second respondent in that writ petition namely, the Controller General of Patents and Designs, to allow the patent application bearing No.1602/NAS/98 filed by the petitioner seeking patent. However at a later stage, during the pendency of the writ petitions, M.P.No.1/2007 came to be filed in that writ petition seeking to delete the prayer for a direction to the Patent Controller to allow the application and it was accordingly ordered. Therefore as on date in the two writ petitions, the Constitutional validity of section 3(d) alone is in challenge, both on the ground that it violates not only Article 14 of the Constitution of India but also on the ground that it is not in compliance to "TRIPS". Both the writ petitions along with the connected miscellaneous petitions were

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admitted by a learned Judge of this court and before the very same learned Judge, at a later stage, all the miscellaneous petitions came up for disposal. We are informed that elaborate arguments were advanced by the learned senior counsels on either side at that stage and on 26.09.2006 learned Judge, who heard these writ petitions with the connected miscellaneous petitions, came to the conclusion that the writ petitions require the attention of a Division Bench of this court, as according to the learned single Judge, the writ petitions involve substantial questions of law. Therefore learned single Judge passed an order directing the Registry to place the entire material papers before the Hon'ble Chief Justice for disposal by a Division Bench. Subsequently, by orders of the Hon'ble Chief Justice, these writ petitions are listed before us. Heard Mr.Soli Sorabji, Mr.Shanthi Bhushan and Mr.Habibulla Badsha, learned senior counsels appearing for the petitioners; Mr.V.T.Gopalan, learned Additional Solicitor General for the Government of India and the Controller of Patents and Designs; Mr.Anand Grover, learned counsel; Mr.P.S.Raman learned senior counsel; Mr.Aravind P Datar learned senior counsel; Mr.K.M.Vijayan learned senior counsel and Mr.Lakshmi Kumaran, learned counsel appearing for the various respondents.

2. In this judgment, for convenience sake, we will hereinafter refer the Patents Act as the "Principal Act"; Ordinance 7/2004 introducing an amendment to section 3(d) of the Act as the "Ordinance"; Amending Act of 2005 amending section 3(d) of the Act as the "Amending Act"; section 3(d) as the amended section and the Act after the amendment as the "Amended Act". The challenge to the amended section is mainly on two grounds namely,

(a) it is not compatible to the agreement on Trade Related aspects of Intellectual Property Rights, hereinafter referred to as "TRIPS" for convenience sake; and

(b) it is arbitrary, illogical, vague and offends Article 14 of the Constitution of India.

For a better understanding of the attack to the amended section, we feel that it is desirable to extract hereunder section 3(d) of the Principal Act; the nature of amendment to that section sought to be brought in by the Ordinance and the amended section itself:

"**Unamended section 3(d)**: The mere discovery of any new property or new use of a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs atleast one new reactant.

Amendment to section 3(d) under Ordinance 7/2004: The mere discovery of any new property or mere new use of a known substance or of the mere use of a known process; machine or aparatus unless such known process results in a new product or employs atleast one new reactant.

Section 3(d) as amended by the Patents (Amendment) Act, 2005 with effect from 01.01.2005: The mere discovery of a new

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form of a known substance **which does not result in the enhancement of the known efficacy of that substance** or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs atleast one new reactant.

Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pureform, particle size isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, **unless they differ significantly in properties with regard to efficacy**."

3. Learned senior counsels appearing for the petitioners took us through the various covenants/clauses in "TRIPS" to argue that the amended section, as it stands today, runs contra to the various articles found incorporated in "TRIPS". The main thrust is with reference to article 27 of "TRIPS". It is contended that article 1(1) of the "TRIPS" mandates every member country to give effect to the provisions of the "TRIPS" and India being a member country, in implementing the various provisions of "TRIPS" brought in the amended section violating their obligations under "TRIPS". It is argued by learned senior counsels that the proposed amendment brought in under the Ordinance is compatible to "TRIPS". However, without any rhyme or reason, the proposed amendment sought to be introduced by the Ordinance had been completely given up and instead, the offending amended section was brought. The sum and substance of the argument advanced by learned senior counsels for the petitioner company is, by bringing in the amended section and the Explanation attached to it, the Union of India had infact not carried out it's obligations arising out of "TRIPS" and instead, by the amended section making that the discovery of a new form of a known substance, **which does not result in the enhancement of the known efficacy of that substance** as not patentable, the right to have an invention patented guaranteed under section 27 of the "TRIPS" is taken away. As far as the attack to the section on the ground of arbitrariness and vagueness thereby offending Article 14 of the Constitution of India, it is argued by Mr.Soli Sorabji, learned senior counsel, that the amended section as it stands today is unworkable. Section 3 of the Act enumerates what are not inventions. Under Article 27 of "TRIPS", all inventions, subject to paragraphs 2 and 3 of that Article, are patentable. Reading Article 27 as a whole, it is argued that the drug invented in the case on hand is patentable. Under the amended section, the patent applicant is required to show that the invention has enhanced efficacy of the known substance. Though the efficacy of a known substance may be well known, yet, unless there are some guidelines in the amended section itself to understand the expression "**enhancement of the known efficacy**" namely, what would be treated as "**enhanced efficacy**", an uncontrolled discretion is given to the Patent Controller to apply his own standards, which may not be uniform, in deciding whether there is enhancement of the known efficacy of that substance. Such wide discretion vested with a Statutory Authority without any guidelines to follow, would result in arbitrary exercise of power. In other words, the Patent Controller may be in a position to decide any case, based on his whims and

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fancies namely, whether there is enhancement in the known efficacy or not. On this short ground, the section must be held to be violative of Article 14 of the Constitution of India. Likewise, in the Explanation attached to the amended section also, there is vagueness. The Explanation declares that all derivatives of a known substance shall be considered to be the same substance unless they "**differ significantly in properties with regard to efficacy**". Derivatives need not be the same substance in all cases. Unless the Explanation contains guidelines as to when a derivative can be held to differ significantly in properties with regard to efficacy, the Patent Controller will have an unguided power to decide the issue, which once again would result in arbitrariness. It is argued by learned senior counsels that though efficacy of a known substance could be clinically found, any discovery of a new form of the said substance or it's derivatives, though by themselves are inventions as defined in the Act, are denied patent based on the amended section containing specified offending clauses namely, it should show enhancement of the known efficacy and that the derivatives should differ significantly in properties with regard to efficacy.

4. Learned senior counsels on the opposite side would vehemently contend that the amended section is definitely compatible to "TRIPS". Even assuming that it is not so, the remedy to have the "TRIPS" agreement complied with in letter and spirit available to the member countries does not lie before the Indian courts but only before the Dispute Settlement Board, hereinafter referred to as "DSB" created under "TRIPS" itself. According to them, even assuming if "TRIPS" confers rights on any citizen/legal entity of a member country, then such person should also approach "DSB" only. "DSB" had been constituted to address all disputes that may arise between member countries and their citizens/legal entity in implementing or not implementing "TRIPS" and that is the exclusive authority to go into those controversies. Therefore the challenge to the validity of the amended section on the ground that it is not compatible to "TRIPS", cannot be legally sustained before Indian courts. It is contended by learned senior counsels and the other counsels on the opposite side that in discharging their obligations under "TRIPS", Government of India had brought in several amendments to the Parent Act and the amended section is one such provision. Every member country is given enough elbow room to bring in a local law in discharging their obligation under "TRIPS" having regard to the various needs of their citizens. India is a welfare country and it's first obligation under the Constitution is to provide good health care to it's citizens. When that is it's priority commitment under the Constitution of India, the Union of India has every right to bring in any local law in discharging their obligations under "TRIPS" to suit to the needs and welfare of it's citizens. On the attack to the amended section that it is vague, arbitrary and therefore unconstitutional, it is argued by learned senior counsels and the other counsels in the opposite camp that the amended section as it stands is workable. The Patent Controllers are all experts having undergone considerable training abroad in this field. The petitioner is not a novice to the field but on the other hand it is one of the pharmaceutical giants in the world. The efficacy of a known substance is well-known and it is definitely known to everyone in the pharmaceutical field. When the efficacy of that substance would stand

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enhanced could also be clinically found by those in the field. The petitioner is not a common man but it is having the expertise behind it. When does the properties in a derivative differ significantly with regard to efficacy could also be scientifically established by the people in the field. Therefore when everyone in the pharmaceutical field understands what is meant by enhancement in the known efficacy of a substance or when it can be said that the derivatives differ significantly in properties with regard to efficacy and the Patent Controller also understands it, the amended section cannot be struck down on the ground of arbitrariness and vagueness. If the Patent Controller, exercising his Statutory power, wrongly rejects the patent application on the ground that the drug is excluded under the amended section, then such a decision could always be corrected by the Appellate Authority and then by the higher forums. In other words, a wrong decision arrived at by the Patent Controller based on wrong application of the amended section cannot be a ground to strike down the said amended section which is otherwise in order. Case law was cited at the Bar by learned counsel Mr.Lakshmikumaran appearing for the opposite party that Indian courts have no jurisdiction to test the validity of a municipal law on the ground that it is in violation of an International Treaty, assuming it is so. It is argued by Mr.Lakshmikumaran, learned counsel, by citing an English Court decision, that a member has a right to make a Law of it's own by breaking an International Treaty, if making such a Law is warranted, to meet the welfare of it's citizens. Responding to the arguments advanced by the learned senior counsels and the other counsels for the opposite party that Indian courts cannot test the validity of the amended section on the ground that it is in violation of an International Treaty, learned senior counsels appearing for the petitioner in each case contended, by showing a precedent, that Indian courts do have the power. It is also argued by them that even assuming for a moment without conceding that an Indian Law cannot be struck down on the ground that it is in violation of an International Treaty, yet, there is no bar, either express or implied, disabling Indian courts to give a declaration that the amended section is in violation of the International Treaty. After broadly stating their respective contentions, R3, R4, R5 & R7, R6, R8 and R9 filed their respective written submissions.

5. On the submissions made by the learned senior counsels on either side, we are of the considered opinion that the following issues arise for consideration in these two writ petitions:

(a) Assuming that the amended section is in clear breach of Article 27 of "TRIPS" and thereby suffers the vice of irrationality and arbitrariness violating Article 14 of the Constitution of India, could the courts in India have jurisdiction to test the validity of the amended section in the back drop of such alleged violation of "TRIPS"? **OR**

Even if the amended section cannot be struck down by this court for the reasons stated above, cannot this court grant a declaratory relief that the amended section is not in compliance of Article 27 of "TRIPS"?.

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(b) If it is held that courts in India have jurisdiction to go into the above referred to issue, then, is the amended section compatible or non-compatible to Article 27 of "TRIPS"?

(c) Dehors issues (a) and (b) referred to above, could the amended section be held to be violative of Article 14 of the Constitution of India on the ground of vagueness, arbitrariness and conferring un-canalised powers on the Statutory Authority?

6. Let us take the first issue.

(a) Assuming that the amended section is in clear breach of Article 27 of "TRIPS" and thereby suffers the vice of irrationality and arbitrariness violating Article 14 of the Constitution of India, could the courts in India have jurisdiction to test the validity of the amended section in the back drop of such alleged violation of "TRIPS" (OR) Even if the amended section cannot be struck down by this court for the reasons stated above, cannot this court grant a declaratory relief that the amended section is not in compliance of Article 27 of "TRIPS"?: In support of the arguments that Indian courts have jurisdiction to decide the issue under consideration, learned senior counsels appearing for the petitioners relied upon the decision of the House of Lords in the case reported in **Equal Opportunities Commission & Another Vs. Secretary of State for Employment [(1994) 1 AII ER Pg.910**]. Employment Protection (Consolidation) Act, 1978 was under consideration in that judgment in the context of discrimination against women alleged. Under that Act, full-time workers, who worked for 16 or more hours a week had to be in continuous employment for two years to qualify for Statutory rights under the Act whereas, part-time workers, who worked between 8 and 16 hours in a week had to be in continuous employment for five years to qualify for the Statutory rights under that Act. That judgment noted that a great majority of full-time employers in the United Kingdom were men while the great majority of part-time workers were women. Equal Opportunities Commission took the view that such discrimination conflicted with the obligations of the United Kingdom under EEC Law namely, Article 119 of EEC Treaty and Council Directives 75/117 (the Equal Pay Directive) and 76/207 (the Equal Treatment Directive). The Secretary of the State declined to accept that the United Kingdom was in breach of it's obligations under Community Law while providing less favourable treatment in the conditions of employment of full-time workers and part-time workers. Therefore, the Equal Opportunities Commission applied for judicial review of the Secretary of State's decision and sought a declaration that the Secretary of State and United Kingdom were in breach of Community Law obligations and an order of mandamus requiring the Secretary of State to introduce Legislation to provide the right for men and women to receive equal pay for equal work. Further reliefs were also asked for. The Secretary of State raised two objections namely, the claim of an individual applicant is a private law claim, which ought not to have been brought against the Secretary of State by way of judicial review and that the Commission had no locus standi to bring the proceedings as it 's case did not involve any decision on justiciable issue susceptible of judicial review. It was further contended **by the Secretary of State that the court had no jurisdiction to declare that United Kingdom or the Secretary of State was**

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in breach of any obligations under the Community Law and that the Divisional Court was not the appropriate forum to determine the substantive issue raised by the applicant. The Divisional Court, among other things, held that **the court only had jurisdiction to declare rights and obligations enforceable under the existing state of the Law and had no jurisdiction to order mandamus requiring the Secretary of State to introduce Legislation to amend the 1978 Act or to declare that he was under a duty to do so.** The Commission as well as the individual applicant appealed to the Court of Appeal, which dismissed the individual applicant's appeal on the ground that her application was essentially a private law claim, which should have been brought against her employer in an Industrial Tribunal and dismissed the Commission's appeal on the ground that the Secretary of State had not made any **"decision".** The Court of Appeal also held that there was no justiciable issue suitable for consideration by way of judicial review. The Commission and the individual appealed to the House of Lords. The House of Lords raised various questions to be addressed by it in that appeal and in our respectful opinion, the decision of the House of Lords on one of the questions raised by it to be addressed, would be relevant for the purpose of the case on hand. We extract that question hereunder:

> "The question is, whether judicial review is available for the purpose of securing a declaration that certain United Kingdom primary Legislation is incompatible with Community Law?"

In deciding that issue, the House of Lords referred to Article 119 of the EEC Treaty, which provides for the following:

> "Equal pay for equal work to men and women; Council Directive (EEC) 75/117 (the equal pay directive); and Article 2 (1) of Council Directive (EEC) 76/207 (the equal treatment directive)".

Section 2 of the European Communities Act, 1972 was also brought to the attention of the House of Lords. It being the telling provision in deciding the issue before us, we extract it hereunder:

> "(1) All such rights, powers, liabilities, obligations and restrictions from time to time created or arising by or under the Treaties and all such remedies and procedures from time to time provided for by or under the Treaties, as in accordance with the Treaties are without further enactment to be given legal effect or used in the United Kingdom shall be recognised and available in law, and be enforced, allowed and followed accordingly; and the expression "enforceable Community right" and similar expressions shall be read as referring to one to which this sub-section applies."

The House of Lords dismissed the appeal of the individual claimant agreeing with the decision of the earlier courts that it was only her private law claim. But however, in deciding the appeal of Equal Opportunities Commission, the House of Lords gave a declaration that Employment Protection (Consolidation) Act, 1978 is incompatible with

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Article 119 of the EEC Treaty and Council Directive (EEC) 75/117 and Council Directive (EEC) 76/207. Therefore learned senior counsels Mr.Soli Sorabji and Mr.Shanthi Bhushan, relying upon this judgment, argued, as they have done earlier, that there is no legal bar for this court to give a simplicitor declaratory relief that the amended section is incompatible with Article 27 of "TRIPS". It is also argued by the learned senior counsels that this court can go into the validity of the amended section, as being not in compliance with Article 27 of "TRIPS", under Article 226 of the Constitution of India, since there is neither express nr implied bar in the Article itself.

7. Learned counsels, in particular, Mr.Anand Grover and Mr.Lakshmikumaran, argued with tremendous ease - as they are shown to possess - stating that the judgment referred to above and relied upon by the learned senior counsels could not be applied to the case on hand on facts. By taking us through the very same judgment, it is argued by them that under section 2(1) of the European Communities Act, 1972, Article 119 of the EEC Treaty with the two Council Directives referred to earlier have been domesticated as a domestic Law in England. When the relevant provision of the EEC Treaty and the Councils Directives stand domesticated by an Act of the State, then it becomes Law of that State enforceable in letter and spirit by the citizens of that State. It is their argument that "TRIPS" do not become Law in India on it's own force without any domestic Law legislated by the Indian Government. Only in discharging their obligations under "TRIPS", several amendments, including the amended section, were brought into the Statute book namely, Patents Act, by the Government. Therefore they argued that when Equal Opportunities Commission case can be distinguished on facts, it would be inappropriate to rely upon the same to hold that a declaratory relief can be granted by this court. As the learned counsels were making their submissions on the above point, Mr.Shanthi Bhushan, learned senior counsel appearing for the petitioner in one of the writ petitions, very fairly conceded and stated that Equal Opportunities Commission's case can be distinguished on facts. We do find, on going through the judgment in Equal Opportunities Commission's case, that the provisions of EEC Treaty and the Councils Directives by an Act of the State was domesticated and therefore all the rights flowing out of the said Treaty and the Directives were available as Law in the United Kingdom, which can be enforceable. Only in that context, we state with respect that the House of Lords has given a declaration as prayed for. Learned counsels appearing for the contesting parties did not rest with the laurel of making us accept and Mr.Shanthi Bhushan to concede that Equal Opportunities Commission case is distinguishable on facts but spared no efforts in advancing arguments in their own way, supported by case laws, that Indian Courts have no jurisdiction either to test the validity of a State Act as being incompatible to an International Treaty namely, Article 27 or even to give a declaration simplicitor that such State Act is not compatible to an International Treaty. We will be failing in our duty if we do not mention that Mr.V.T.Gopalan, learned Additional Solicitor General was leading from the forefront the entire band of lawyers in the opposite camp by contending that this court has no jurisdiction at all to go into the issue referred to above; in any event the amended section is in compliance with Article 27 of "TRIPS" and that there is no violation of Article 14 of the

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Constitution of India. Mr.Lakshmikumaran, learned counsel appearing for R5 and R7 relied upon a judgment reported in **1966-3-All England Law Reports Pg.871 (Salomn Vs. Commissioner of Customs**) to contend that if any domestic court is approached challenging a municipal law on the ground that it violates International Law, then, the remedy for that lies in a forum other than the domestic court. In that judgment, the Court of Appeal through LORD DIPLOCK held as hereunder:

> "If the terms of the legislation are clear and unambiguous, they must be given effect to whether ornot they carry our Her Majesty's treaty obligations, for the sovereign power of the Queen in Parliament extends to breaking treaties [(see Ellerman Lines, Ltd. Vs. Murray (4)], and any remedy for such a breach of an international obligation lies in a forum other than Her Majesty's own courts."

The above extracted passage refers to an earlier English decision. The learned English Judge, in the latter portion of his judgment, had reiterated that Ellerman Lines Limited's case is the authority for the proposition that when a domestic law is challenged on the ground of it being in violation of an International Treaty, domestic courts would have no jurisdiction. In our considered opinion, this is the direct judgment on the point. We have already noted that the judgment in Equal Opportunities Commission case is distinguishable on facts.

8. Even otherwise, we are of the considered view that in whichever manner one may name it namely, International Covenant, International Treaty, International Agreement and so on and so forth, yet, such documents are essentially in the nature of a contract. In **Head Money cases namely, the judgment of the Supreme Court of the United States reported in 112 U.S. 580**, it is held as follows:

> "A treaty is primarily a compact between independent Nations, and depends for the enforcement of its provisions on the honor and the interest of the governments which are parties to it."

Therefore there cannot be any difficulty at all in examining such treaties on principles applied in examining contracts. Under these circumstances, when a dispute is brought before a court arising out of an International Treaty, courts would not be committing any error in deciding the said dispute on principles applicable to contracts. In other words, the court has to analyse the terms of such International Treaty; the enforceability of the same; by whom and against whom; and if there is violation, is there a mechanism for solving that dispute under the treaty itself? Based on such construction of the International Treaty namely, "TRIPS", it is argued very strenuously by the learned counsels appearing for the contesting parties that there is a settlement mechanism under the Treaty itself and therefore even assuming without conceding that the petitioner has the right to enforce the terms of the said Treaty, yet, he must go only before the Dispute Settlement Body provided under the "TRIPS" itself. Article 64 of "TRIPS" is pressed into service to sustain this point. It is contended by Mr.Anand Grover learned counsel that the settlement

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mechanism provided under Article 64 of "TRIPS" is governed by the procedure as understood by the World Trade Organisation. Mr.Anand Grover learned counsel took us through the said Dispute Settlement Understanding. Article 1 of the Dispute Settlement Understanding, defines the areas covered under that Rule. Article 1 declares that the agreements listed in Appendix 1 to the said Rule would be covered by the procedure. "TRIPS" is mentioned as one of the agreements in Appendix 1 (B) - Annexure 1C. We have been taken through the above referred to Rules and Procedures governing the settlement of disputes and we find that it contains comprehensive provisions for resolving the disputes arising out of any agreements enumerated in Appendix 1 to that Rules. Under the Rules there is a Dispute Settlement Body. The manner of it's constitution is also provided therein. Various steps to sort out the problem arising out of an agreement are provided therein. Article 17 of the Rules referred to above provides an appellate review against the order passed by the panel. Therefore we have no difficulty at all that Article 64 of "TRIPS" read with World Trade Organisation's understanding on Rules and Procedures governing the settlement of disputes provides a comprehensive settlement mechanism of any dispute arising under the agreement. Article 3 of the Rules declares that the dispute settlement system of the World Trade Organisation is to provide security and predictability to the multilateral trading system. When such a comprehensive dispute settlement mechanism is provided as indicated above and when it cannot be disputed that it is binding on the member States, we see no reason at all as to why the petitioner, which itself is a part of that member State, should not be directed to have the dispute resolved under the dispute settlement mechanism referred to above. Several nations in the world are parties to "TRIPS" as well as the "WTO" agreement. The agreements are discussed, finalised and entered into at the higher level of the nations participating in such meeting. Therefore it is binding on them. When such participating nations, having regard to the terms of the agreement and the complex problems that may arise out of the agreement between nation to nation, decide that every participating nation shall have a Common Dispute Settlement Mechanism, we see no reason at all as to why we must disregard it. As we began saying that any International Agreement possesses the basic nature of an ordinary contract and when courts respect the choice of jurisdiction fixed under such ordinary contract, we see no compelling reasons to deviate from such judicial approach when we consider the choice of forum arrived at in International Treaties. Since we have held that this court has no jurisdiction to decide the validity of the amended section, being in violation of Article 27 of "TRIPS", we are not going into the question whether any individual is conferred with an enforceable right under "TRIPS" or not. For the same reason, we also hold that we are not deciding issue No.(b) namely, whether the amended section is compatible to Article 27 of "TRIPS" or not.

9. We also carefully applied our mind as to whether we can give a declaratory relief in exercise of the power under Article 226 of the Constitution of India? We have already found that the judgment in Equal Opportunities Commission case is not a precedent for giving such a declaration. In the judgment reported in **AIR 1951 SC Pg.41 (Charanjit Lal Vs. Union of India)** and the judgment reported in **AIR 1959 SC Pg.725 (K.K.Kochunni Vs. State of Madras)** the Supreme Court was considering the

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power of the court under Article 32 of the Constitution of India to give a declaratory relief. Both the judgments were rendered by two Constitution Benches of the Supreme Court. The Chief Justice of India presided the Constitution Bench in the latter judgment and the said Hon'ble Judge also constituted the coram in the earlier judgment. We extract the relevant portion in paragraph No.45 of the earlier judgment of the Supreme Court:

> "As regards the other point, it would appear from the language of Article as of the Constitution that the sole object of the article is the enforcement of fundamental rights guaranteed by the Constitution. A proceeding under this Article cannot really have any affinity to what is known as a declaratory suit."
>
> "Any way, Article 32 of the Constitution gives us very wide discretion in the matter of framing our writs to suit the exigencies of particular cases, and the application, of the petitioner cannot be thrown out simply on the ground that the proper writ or direction has not been prayed for."

In the latter case, the power of the court to grant declaratory relief came up for consideration. The Constitutionality of Madras Act 32/55 was challenged as infringing fundamental rights under Article 19(1)(f) and Article 31(1). The point that appears to have been argued in favour of granting a declaratory decree, as noted therein, is extracted hereunder:

> "The next argument in support of the objection as to the maintainability of these petitions is thus formulated: The impugned Act is merely a piece of a declaratory legislation and does not contemplate or require any action to be taken by the State or any other person and, therefore, none of the well known prerogative writs can afford an adequate or appropriate remedy to a person whose fundamental right has been infringed by the mere passing of the Act. If such a person challenges the validity of such an enactment, he must file a regular suit in a court of competent jurisdiction for getting a declaration that the law is void and, therefore, cannot and does not affect his right. In such a suit he can also seek consequential reliefs by way of injunction or the like, but he cannot avail himself of the remedy under Article 32. In short, the argument is that the proceeding under Article 32 cannot be converted into or equated with a declaratory suit under section 42 of the Specific Relief Act."

The Hon'ble Judges of the Supreme Court in that case referred to the earlier judgment of the Supreme Court referred to above as well as the judgments reported in **AIR 1950 SC 163** (Rashid Ahmed Vs. Municipal Board, Kairana); **AIR 1954 SC 440** (Basappa Vs. T. Nagappa); **AIR 1954 SC 229** (Ebrahim Vadir Mavat Vs. State of Bombay) and held as hereunder:

> "But on a consideration of the authorities it appears to be well established that this Court's powers under Article 32 are

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wide enough to make even a declaratory order where that is the proper relief to be given to the aggrieved party. The present case appears to us precisely to be an appropriate case, if the impugned Act has taken away or abridged the petitioners' right under Article 19(1)(f) by its own terms and without anything more being done and such infraction cannot be justified. If, therefore, the contentions of the petitioners be well founded, as to which we say nothing at present, a declaration as to the invalidity of the impugned Act together with the consequential relief by way of injunction restraining the respondents and in particular respondents 2 to 17 from asserting any rights under the enactment so declared void will be the only appropriate reliefs which the petitioners will be entitled to get. Under Article 32 we must, in appropriate cases, exercise our discretion and frame our writ or order to suit the exigencies of this case brought about by the alleged nature of the enactment we are considering."

Therefore it is clear that when an enactment infringes the fundamental rights and a challenge is made to that on that ground, the Hon'ble Supreme Court of India had said that it should not hesitate to grant a declaratory relief under Article 32 of the Constitution of India. In **AIR 1975 SC 1810 (S.G.Films Exchange Vs. Brijnath Singhji) and AIR 1976 SC 888 (Vaish Degree College Vs. Lakshmi Narain**), the Supreme Court held that the relief of declaration under the provisions of the Specific Relief Act is purely discretionary. In the latter judgment, the Supreme Court went on to hold that while exercising it's discretionary powers, the court must keep in mind the well settled principles of justice and fair play and should exercise the discretion only if the ends of justice require it, for justice is not an object which can be administered in vacuum. As rightly contended by Mr.P.S.Raman learned senior counsel, we have to decide in this case whether the amended section is bad in law for lack of legislative competency or it violates Part-III of the Constitution of India or any other provisions in the Constitution. We also thought whether ends of justice require giving a helping legal hand to the petitioner. The amended section does not take away in toto the right of the petitioner to carry on the trade. It is contended by Mr.P.S.Raman learned senior counsel that the petitioner gets only a proprietary right over the patent lasting for a fixed tenure and beyond that it does not get anything else. We agree with him on this point. We also find that ends of justice, on the facts of this case, is not in favour of the petitioner, which would disable us from exercising our discretionary jurisdiction. It has been held by the Supreme Court in an unreported judgment in **Katakis Vs. Union of India (W.P.No.54/68 dated 28.10.1968)** that no declaration would be given where it would serve no useful purpose to the petitioner. We thought what will happen if a declaratory relief is given as asked for, assuming for a moment that we have the jurisdiction. It is a settled position in law that nobody can compel the Parliament to enact a Law. If that is the position, then, assuming that we give a declaration as prayed for namely, the amended provision is not in the discharge of India's obligation under Article 27 of "TRIPS", even then, we fail to see for what use the petitioner can put it. Even if a consequential relief is not asked for, courts have held, depending upon the facts available in each

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case, that a declaratory relief could be granted, provided, it is shown that such a declaratory relief would be a stepping stone to claim relief at some other stage. Having that in our mind, when we again thought aloud as to what use to which such a declaratory relief, if granted to the petitioner, could be put to and we find that there is no scope at all to put in use the declaratory relief, if granted, at a later point of time. In other words, the declaratory relief, even if granted, would be only on paper, on the basis of which, the petitioner cannot claim any further relief in the Indian courts. Only in this context, we extract hereunder the relevant portion in the unreported judgment of the Supreme Court in **Katakis case** referred to above, which was rendered by a Constitution Bench consisting of Hon'ble Judges Sikri, Bachawat, Mitter, Hegde and Grover, JJ:

> "It is not even stated that the petitioner did not apply because of the canalisation scheme. **The Supreme Court in appropriate circumstances can give a declaration that a particular order or scheme violates the provisions of the constitution but the Supreme Court will not give such a declaration unless it is certain that the declaration will serve some useful purpose to the petitioners.** Even if the declaration is given the petitioners may possibly not apply for a licence; if they do apply, the conditions of import and export may change drastically by the time the application is filed, or the policy of the Government may change. But if the petitioners had applied for the licence on the basis that the canalisation scheme was invalid, their application would have been processed by the authorities apart from the canalisation scheme but in accordance with law. The Court declined to go into the question of the validity of the canalisation scheme."

Therefore, for the reasons stated above, we find that the petitioner in each writ petition is not entitled to even the declaratory relief.

10. Let us now take the last issue for consideration.

> " **(c) Dehors issues (a) and (b) referred to above, could the amended section be held to be violative of Article 14 of the Constitution of India on the ground of vagueness, arbitrariness and conferring un-canalised powers on the Statutory Authority**?"

The main grounds of attack to the validity of the amended section are that, it is vague, arbitrary and confers uncanalised powers on the Statutory Authority. The Statutory Authority in this case is the Patent controller. There is no doubt that he is exercising a quasi-judicial function namely, considers the patent claim application in the context of the objections received; hears parties on both sides and then passes an order, either granting the patent or rejecting the patent application, by giving reasons. Prior to the amended section was brought into the Statute book by the Patent (Amendment) Act, 2005 (Act 15/2005) with effect from 01.01.2005, it was preceded by Ordinance 7/2004 containing the proposed amendment to be made to section 3(d). In the earlier portion of this judgment, we have extracted section 3(d) as it originally stood; section 3

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(d) as sought to be brought in by Ordinance 7/2004 and the amended section itself. India is a founder member of the World Trade Organisation, in short, "WTO" and as such a signatory of "TRIPS", which itself is an Annexure to the "WTO" agreement. There is no dispute that under "TRIPS" agreement, India has to permit product patent in all fields of technology, including medicines and drugs, with effect from 01.01.2005. Pending bringing in comprehensive provisions, the Union Government of India made some temporary provisions in the Act itself, which temporary provisions came to an end on and with effect from the coming into force of Act 15/2005. Prior to Amending Act 15/2005, there were Amending Acts 17/1999 and 38/2002. In the affidavits filed in support of both the writ petitions, Parliamentary Debates on Ordinance 7/2004, in the context of the amendment to section 3(d) are extensively extracted. A speech from the Member of the Parliament from Kottayam in that regard and the reply in regard thereto from the Hon'ble Minister of Commerce are found so extracted. The Parliamentarians appear to have been opposing the amendment to section 3(d) on the ground that, if the amendment as indicated in the Ordinance is allowed to be brought in, then, there is a fear of the common man being denied access to life saving medicines and it would encourage evergreening. The reply by the Hon'ble Minister shows that he was aware of the impending problem namely, "evergreening" and the action which the Hon'ble Minister intend to take. Admittedly, the amended section is not the amendment sought to be introduced by Ordinance 7/2004. It is argued by learned senior counsels appearing for the petitioners that had the amendment proposed under Ordinance 7/2004 been brought into the Act in the form in which it was shown, then, it would have been in strict compliance to "TRIPS". But instead, the amended section has been brought into the Statute book. It is clear that the amended section appears to have been drafted in a great hurry without realising that it is likely to be struck down on the ground that it is incompatible with "TRIPS" (we have already held that we cannot go into that question) and also being in violation of Article 14 of the Constitution of India (the later point alone survives now). Since the ground of attack based on vagueness and arbitrariness and conferring uncanalised power to the Statutory Authority over-lap each other and therefore our points of discussion are also likely to over-lap each other. So we have decided to take up all the three individual grounds raised for decision in a consolidated manner.

11. According to the learned senior counsels, the amended section is bad for the following reasons:

Under Ordinance 7/2004 mere discovery of a new property is not treated as an invention. But however, in the amended section, a further clause is added to the effect that the discovery of a new form of a known substance should result in the enhancement of the known efficacy of that substance and if it does not, then, it is not an invention. Therefore the argument goes on the validity of the amended section that, in the absence of any guideline in the amended section or the Act itself as to how to find out, when there is enhancement of the known efficacy of the substance from which the discoveries are made, then, an unguided discretion is vested with the Statutory Authority and therefore the amended section is bad in law. They would then argue that to make the matter worse, to the

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amended section, an Explanation is added, by which, a deeming fiction is created to the effect that all salts, esters, etc., etc., if derived from a known substance, then, such derivatives are also considered to be the same substance, unless the derivatives are shown to differ significantly in properties with regard to efficacy. It is argued that all derivatives need not necessarily be the same substance and therefore the deeming fiction created by the Explanation is bereft of any guidelines and is bad in Law. It is argued that there must be some guidance or guideline in the Act itself as to when a derivative shall be held to be differing significantly in properties with regard to efficacy. In other words, the submission is that, both the amended section as well as the Explanation to the amended section must prescribe in clear terms for the Authority constituted under the Act, the guidelines to decide in what circumstances it can be held that the discovery of a new form of a known substance had resulted in the enhancement of the known efficacy of that substance and when the derivatives are found to differ significantly in properties with regard to efficacy. Though the expression "efficacy" has a definite meaning, yet, no definite meaning could be attributed to the expression "**enhancement of the known efficacy**" and "**differ significantly in properties with regard to efficacy**". These expressions are ambiguous. Therefore it is argued by learned senior counsels that when it is possible for the Legislature to explain what is meant by "**enhancement of a known efficacy**" and "**differing significantly in properties with regard to efficacy**", the Legislature is duty bound to clear the ambiguity. According to them, if this ambiguity is not cleared, then, there is every chance for the Statutory Authority to exercise it's power to it's whims and fancies. Therefore the amended section is also irrational. Opposing these arguments, learned Additional Solicitor General of India and the other learned senior counsels and learned counsels for the contesting parties would submit that having regard to the field in which the amended section is to operate; the technological and scientific research oriented advances already made and likely to be made in the coming future and which may be a continuing process for all time to come, the Legislature thought it fit to use only general expressions in the Act, leaving it for the Statutory Authority to apply it's mind to the various facts that are brought to it's notice and then find out whether the invented drug is within the mischief of the amended section or outside it. Therefore it would be unwise to fix any specific formula to be applied, as a matter of static measure, to find out whether the new form of a known substance resulted in the enhancement of the known efficacy or the derivatives differ significantly in properties with regard to efficacy. Having regard to the inventions that are made and are likely to be made in the time to come, it is humanly impossible to prescribe a fixed formula to decide the issue as indicated above and if it is so done without even knowing what would be the new discoveries, then, the hands of the Statutory Authority would be completely tied to a fixed and definite situation, from which it cannot even wriggle out. Discoveries that are likely to be made in the future may not be alike and they may vary from each other in their therapeutic effect and properties. Learned Additional Solicitor General of India and other learned senior counsels appearing for the pharmaceutical companies would argue that in the given situation, the amended section as it stands today is a classic Legislation by itself thereby giving enough room in the joints for the Statutory

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Authority to evaluate the materials placed before him in a case to case basis; analyse the comparative details that are likely to be placed before him and then arrive at a decision to say whether the discovery / derivative is an invention or not. Therefore the Statutory Authority has been given a discretion, which he has to exercise based on the details to be placed before him. In exercising such a discretionary power vested in the Statutory Authority, if it is found that he has exercised that discretionary power wrongly or abused it, then, such an error can always be corrected by higher forums, which is provided for in the Act itself and thereafter, by the courts of law. In other words, a provision of law cannot be struck down on the ground that the Authority exercising the power under that provision is likely to misuse it, unless it is shown that the said provision itself ex-facie is violative of Article 14 of the Constitution of India, which is not the case here. When there would be enhancement of the known efficacy and when it would be found that the derivatives differ significantly in properties with regard to efficacy, would vary from discovery to discovery. It is then argued that the Explanation to the amended section does not create any additional criteria but it only explains the amended section itself. Debates in Parliament could not be the basis for interpreting the Statute, is their last submission.

12. In the light of the arguments advanced by the learned senior counsels all-round, we went through the entire records. We do find that section 3(d) as shown in Ordinance 7/2004 had not been reproduced in the form in which it was shown in the Act. Therefore the amended section definitely differs from the form in which it was put in the Ordinance. The amended section is not confined only to drugs as it deals with machines and apparatuses as well. But however, we are clear in our mind that the portions of the amended section and the Explanation under attack is definitely referable only to the pharmacology field namely, drugs. Since Parliamentary debates have been relied upon by the learned senior counsels for the petitioners to argue that since the amended section appears to be a hurriedly brought out Legislation, the Parliamentary debates can be looked into to find out whether the amended section is ex-facie violative of Article 14 of the Constitution of India. We went through the case laws brought to our notice by Mr.V.T.Gopalan, learned Additional Solicitor General of India; Mr.P.S.Raman learned senior counsel and Mr.Anand Grover. Mr.Shanthi Bhushan, learned senior counsel relied upon one or two judgments so brought to our notice. We also tried to find out as to whether the "**statement of objects and reasons**" of an Act would help the court to analyse the provision which the writ petitioner alleges is violating Article 14 of the Constitution of India. The earliest judgment of the Indian court brought to our notice in this context by Mr.P.S.Raman learned senior counsel, is the judgment of the Supreme Court reported in **AIR 1952 SC Pg.369 (Aswini Kumar Vs. Arabinda Bose)**, in which the law on the subject is laid down as hereunder:

> "The speeches made by the members of the House in the course of the debate are not admissible as extrinsic aids to the interpretation of statutory provisions: AIR 1952 SC 366."

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"The Statement of Objects and Reasons, seeks only to explain what reasons induced the mover to introduce the bill in the House and what objects be sought to achieve. But those objects and reasons may or may not correspond to the objective which the majority of members had in view when they passed it into law. The Bill may have undergone radical changes during its passage through the House or Houses, and there is no guarantee that the reasons which led to the introduction and the objects thereby sought to be achieved have remained the same throughout till the Bill emerges from the House as an Act of the Legislature, for they do not form part of the Bill and are not voted upon by the members. The Statement of Objects and Reasons

appended to the Bill should be ruled out as an aid to the construction of a statute."

Therefore from the above pronouncement, it is clear that when the Bill is debated, new things are likely to emerge and the emerging new things may be taken into account while a final shape is given to the Bill before it was brought into an Act. The statement of objects and reasons also stands excluded as extrinsic aid to the construction of a Statute. The next in line is the judgment of the Supreme Court reported in **(1986) 2 SCC Pg.237 (Girdhari Lal & Sons Vs. Balbir Nath Mathur**) wherein, on the subject of interpretation of Statutes, the Supreme Court had laid down the law as hereunder:

"7. Parliamentary intention may be gathered from several sources. First, of course, it must be gathered from the statute itself, next from the preamble to the statute, next from the Statement of Objects and Reasons, thereafter from parliamentary debates, reports of committees and commissions which preceded the legislation and finally from all legitimate and admissible sources from where there may be light. Regard must be had to legislative history too."

"8. Once parliamentary intention is ascertained and the object and purpose of the legislation is known, it then becomes the duty of the court to give the statute a purposeful or a functional interpretation. This is what is meant when, for example, it is said that measures aimed at social amelioration should receive liberal or beneficent construction. Again, the words of a statute may not be designed to meet the several uncontemplated forensic situations that may arise. The draftsman may have designed his words to meet what Lord Simon of Glaisdale calls the "primary situation". It will then become necessary for the court to impute an intention to Parliament in regard to "secondary situations". Such "secondary intention" may be imputed in relation to a secondary situation so as to best serve the same purpose as the primary statutory intention does in relation to a primary situation."

Mr. Anand Grover, learned counsel appearing for one of the pharmaceutical companies brought to our notice the judgment of the Supreme Court in the

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case reported in **(1994) 5 SCC Pg.593 (K.S.Paripoornan Vs. State of Kerala**), wherein, the Supreme Court had held on the Law of Interpretation of Statutes as hereunder:

> "As regards the Statement of Objects and Reasons appended to the Bill the law is well settled that the same cannot be used except for the limited purpose of understanding the background and the state of affairs leading to the legislation but it cannot be used as an aid to the construction of the statute. (See Aswini Kumar Ghosh Vs. Arabinda Bose; State of West Bengal Vs. Subodh Gopal Bose per Das, J; State of West Bengal Vs. Union of India). Similarly, with regard to speeches made by the members in the House at the time of consideration of the Bill it has been held that they are not admissible as extrinsic aids to the interpretation of the statutory provisions though the speech of the mover of the Bill may be referred to for the purpose of finding out the object intended to be achieved by the Bill. (See State of Travancore, Cochin Vs. Bombay Co. Ltd. And Aswini Kumar Vs. Arabinda Bose)."

Learned senior counsels on either side also relied upon a judgment of the Supreme Court reported in **(1998) 4 SCC Pg.626 (P.S.Narasimha Rao Vs. State (CBI/SPE**), wherein, it has been held as follows:

> "It would thus be seen that as per the decisions of this court the statement of the Minister who had moved the Bill in Parliament can be looked at to ascertain the mischief sought to be remedied by the legislation and the object and purpose for which the legislation is enacted. The statement of the Minister who had moved the Bill in Parliament is not taken into account for the purpose of interpreting the provisions of the enactment. The decision in Pepper Vs. Hari permits reference to the statement of the Minister or other promoter of the Bill as an aid to construction of legislation which is ambiguous or abscure or the literal meaning of which leads to an absurdity provided the statement relied upon clearly discloses the mischief aimed at or the legislative intention lying behind the ambiguous or obscure words and that such a statement of the Minister must be clear and unambiguous."

In **Narasimha Rao's** case referred to supra, the Supreme Court had held that the statement of the Minister, who makes the Bill in Parliament can be looked at, to ascertain the mischief sought to be remedied by the Legislation. We now go back to **Girdhari Lal's case** referred to supra , wherein, the Supreme Court had held as follows:

> "Our own court has generally taken the view that ascertainment of legislative intent is a basic rule of statutory construction and that a rule of construction should be preferred which advances the purpose and object of a legislation and that though a construction, according to plain language, should ordinarily be adopted, such a construction should not be adopted where it leads to anomalies, injustices or absurdities, vide

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K.P.Varghese Vs. ITO; State Bank of Travancore Vs. Mohd. M.Khan; Som Prakash Rekhi Vs. Union of India; Ravula Subba Rao Vs. CIT; Govindlal Vs. Agricultural Produce Market Committee and Babaji Kondaji Vs. Nasik Merchants Co-op. Bank Ltd."

If we read the Parliamentary debate on Ordinance 7/2004, it appears that there was a wide spread fear in the mind of the members of the House that if section 3(d) as shown in Ordinance 7/2004 is brought into existence, then, a common man would be denied access to life saving drugs and that there is every possibility of "evergreening". The reply by the Hon'ble Minister for Commerce shows that the Hon'ble Minister was sure that Ordinance 7/2004 would prevent "evergreening". The Parliamentary debates also show that the Hon'ble Minister was concerned with the other issues as well. Therefore it is clear to our mind that section 3(d) brought by Amending Act 15/2005 is as a result of debates on Ordinance 7/2004 in the Parliament and due to debates change in the form is unavoidable and permissible, it is not possible to sustain the arguments advanced by the learned senior counsels that having shown section 3(d) in a particular form in Ordinance 7/2004 and bringing it in a totally different form in Amending Act 15/2005, the amending section ex-facie stands in violation of Article 14 of the Constitution of India.

13. Let us now test the argument advanced before this court by learned Senior Counsels on the validity of the amended section on the touchstone of Article 14 of the Constitution of India. As we understand the amended section, it only declares that the very discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance, will not be treated as an invention. The position therefore is, if the discovery of a new form of a known substance must be treated as an invention, then the Patent applicant should show that the substance so discovered has a better therapeutic effect. Darland's Medical Dictionary defines the expression "**efficacy**" in the field of Pharmacology as "**the ability of a drug to produce the desired therapeutic effect**" and "**efficacy**" is independent of potency of the drug. Dictionary meaning of "**Therapeutic**", is healing of disease – having a good effect on the body." Going by the meaning for the word "**efficacy**" and "**therapeutic**" extracted above, what the patent applicant is expected to show is, how effective the new discovery made would be in healing a disease / having a good effect on the body? In other words, the patent applicant is definitely aware as to what is the "**therapeutic effect**" of the drug for which he had already got a patent and what is the difference between the therapeutic effect of the patented drug and the drug in respect of which patent is asked for. Therefore it is a simple exercise of, though preceded by research, - we state – for any Patent applicant to place on record what is the therapeutic effect / efficacy of a known substance and what is the enhancement in that known efficacy. The amended section not only covers the field of pharmacology but also the other fields. As we could see from the amended section, it is made applicable to even machine, apparatus or known process with a rider that mere use of a known process is not an invention unless such a known process results in a new product or employs atleast one new reactant. Therefore the amended section is a comprehensive provision covering all fields of technology, including the field of pharmacology. In our opinion, the explanation

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would come in aid only to understand **what is meant by the expression "resulting in the enhancement of a known efficacy"** in the amended section and therefore we have no doubt at all that the Explanation would operate only when discovery is made in the pharmacology field. In **1989 (4) SCC Pg.378 (Aphali Pharma. Ltd. Vs. State of Maharashtra**), in laying down the law on "Explanation", the Supreme Court held as hereunder:

> "33. An Explanation, as was found in Bihta Marketing Union Vs. Bank of Bihar, may only explain and may not expand or add to the scope of the original section. In State of Bombay Vs. United Motors, it was found that an Explanation could introduce a fiction or settle a matter of controversy. Explanation may not be made to operate as "exception" or "proviso". The construction of an Explanation, as was held in Collector of Customs Vs. G.Dass & Co., must depend upon its terms and no theory of its purpose can be entertained unless it is to be inferred from the language used. It was said in Burmah Shell Oil Ltd. Vs. CTO, that the Explanation was meant to explain the article and must be interpreted according to its own tenor and it was an error to explain the Explanation with the aid of the article to which it was annexed. We have to remember what was held in Dattatraya Govind Mahajan Vs. State of Maharashtra, that mere description of a certain provision, such as "Explanation" is not decisive of its true meaning. It is true that the orthodox function of an Explanation is to explain the meaning and effect of the main provision to which it is an explanation and to clear up any doubt or ambiguity in it, but ultimately it is the intention of legislature which is paramount and mere use of a label cannot control or deflect such intention. State of Bombay Vs. United Motors laid down that the interpretation must obviously depend upon the words used therein, but this must be borne in mind that when the provision is capable of two interpretations, that should be adopted which fits the description. An Explanation is different in nature from a Proviso for a Proviso excepts, excludes or restricts while an Explanation explains or clarifies. Such explanation or clarification may be in respect of matters whose meaning is implicit and not explicit in the main section itself. In Hiralal Ratanlan Vs. State of U.P it was ruled that if on a true reading of an Explanation it appears that it has widened the scope of the main section, effect be given to legislative intent notwithstanding the fact that the legislature named that provision as an Explanation. In all these matters courts have to find out the true intention of the legislature. In D.G.Mahajan Vs. State of Maharashtra, this court said that legislature has different ways of expressing itself and in the last analysis the words used alone are repository of legislative intent and that if necessary an Explanation must be construed according to its plain language and not on any a priori consideration."

In **2006 (8) SCC 613 ((Hardev Motor Transport Vs. State of M.P.)**, on the role of "Explanation", the Supreme Court held as hereunder:

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"31. The role of an Explanation of a statute is well known. By inserting an Explanation in the Schedule of the Act, the main provisions of the Act cannot be defeated. By reason of an Explanation, even otherwise, the scope and effect of a provision cannot be enlarged. It was so held in S.Sundaram Pillai Vs. V.R.Pattabiraman in the following terms: (SCC p.613, para 53)

"53. Thus, from a conspectus of the authorities referred to above, it is manifest that the object of an Explanation to a statutory provision is-

(a) to explain the meaning and intendment of the Act itself,

(b) where there is any obscurity or vagueness in the main enactment, to clarify the same so as to make it consistent with the dominant object which it seems to subserve,

(c) to provide an additional support to the dominant object of the Act in order to make it meaningful and purposeful.

(d) an Explanation cannot in any way interfere with or change the enactment or any part thereof but where some gap is left which is relevant for the purpose of the Explanation, in order to suppress the mischief and advance the object of the Act it can help or assist the court in interpreting the true purport and intendment of the enactment, ..."

(See also Swedish Match AB Vs. Securities & Exchange Board of India)."

In this case we find that the Explanation creates a deeming fiction of derivatives of a known substance are deemed to be the same substance unless they differ significantly in properties with regard to efficacy. Therefore it is clear from the amended section and the Explanation that in the pharmacology field, if a discovery is made from a known substance, a duty is cast upon the patent applicant to show that the discovery had resulted in the enhancement of a known efficacy of that substance and in deciding whether to grant a Patent or not on such new discovery, the Explanation creates a deeming fiction that all derivatives of a known substance would be deemed to be the same substance unless it differ significantly in properties with regard to efficacy. In our opinion, the amended section and Explanation give importance to efficacy. We have already referred to the meaning of **"efficacy"** as given in Dorland's Medical Dictionary. Scientifically it is possible to show with certainty what are the properties of a **"substance"**. Therefore when the Explanation to the amended section says that any derivatives must differ significantly in properties with regard to efficacy, it only means that the derivatives should contain such properties which are significantly different with regard to efficacy to the substance from which the derivative is made. Therefore in sum and substance what the amended section with the Explanation prescribes is the test to decide whether the discovery is an invention or not is that the Patent applicant should show the discovery

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has resulted in the enhancement of the known efficacy of that substance and if the discovery is nothing other than the derivative of a known substance, then, it must be shown that the properties in the derivatives differ significantly with regard to efficacy. As we stated earlier, due to the advanced technology in all fields of science, it is possible to show by giving necessary comparative details based on such science that the discovery of a new form a of known substance had resulted in the enhancement of the known efficacy of the original substance and the derivative so derived will not be the same substance, since the properties of the derivatives differ significantly with regard to efficacy. As rightly contended by learned Additional Solicitor General India and the leaned Senior Counsels and learned counsels for the Pharmaceutical Company opposing the Writ that the writ petitioner is not a novice to the pharmacology field but it, being pharmaceutical giant in the whole of the world, cannot plead that **they do not know what is meant by enhancement of a known efficacy and they cannot snow that the derivatives differ significantly in properties with regard to efficacy.** Mr.P.S.Raman learned senior counsel argued that the Legislature, while enacting a Law, is entitled to create a deeming fiction and for that purpose, brought to our notice a judgment of the Supreme Court reported in **AIR 1988 SC 191 (M/s.J.K.Cotton Spinning and Weaving Mills Ltd. Vs. Union of India**) where, in paragraph 40, the Supreme Court had said that **"the Legislature is quite competent to enact a deeming provision for the purpose of assuming the existence of a fact which does not really exist."** It is also stated in the very same paragraph that **"it is well settled that a deeming provision is an admission of the non-existence of the fact deemed."**

14. It is argued by learned Senior Counsels for the writ petitioners that it is possible for the Parliament to define in the Act itself what is meant by **enhancement of a known efficacy** and what is meant by **differing significantly in properties with regard to efficacy**. The above expressions are vague and ambiguous by themselves and therefore the meaning of such expressions ought to have been given in the Act or the amended section. Therefore when the meaning is not so given, then the vagueness and ambiguity in the provision would result in arbitrary exercise of power by the statutory authority. Opposing this argument, learned Additional Solicitor General of India would contend that Parliament is not an expert; it cannot foresee the future contingencies which may arise, when they enact an Act; therefore the Parliament always thinks it wise to use only general expressions in the Statute leaving it to the Court to interpret it depending upon the context in which it is used and the facts that are made available in each case. For this purpose, learned Additional Solicitor General brought to our notice the judgment of the Supreme Court reported in **1995 Supp. (1) SCC 235 (Benilal Vs. State of Maharashtra) and 1980 (1) SCC 340 (Registrar of Co-op. Societies Vs. K.Kunjabmu).** Mr.P.S.Raman, learned senior counsel in supporting the argument of learned Additional Solicitor General that the Parliament cannot foresee things that may arise in the future, brought to our notice the judgment of the English Court reported in (**1949) 2 All England Law Reports 155 (Seaford Court Estates Vs. Asher**), to understand and realise whether it would be possible at all to foresee things that may arise in the future when a Statute comes up for consideration before the Houses and what would

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be the duty of the Judge before whom interpretation of such a Statute arise for consideration. The Court of Appeal in that judgment had laid down the Law in that context as hereunder:

> "Whenever a statute comes up for consideration, it must be remembered that it is not within human powers to foresee the manifold sets of facts which may arise, and, even if it were, it is not possible to provide for them in terms free from all ambiguity. The English language is not an instrument of mathematical precision. Our literature would be much the poorer if it were. This is where the draftsmen of Acts of Parliament have often been unfairly criticised. A Judge, believing himself to be fettered by the supposed rule that he must look to the language and nothing else, laments that the draftsmen have not provided for this or that, or have been guilty of some or other ambiguity. It would certainly save the judges trouble if Acts of Parliament were drafted with divine prescience and perfect clarity. In the absence of it, when a defect appears a judge cannot simply fold his hands and blame the draftsman. He must set to work on the constructive task of finding the intention of Parliament, and he must do this not only from the language of the statute, but also from a consideration of the social conditions which gave rise to it and of the mischief which it was passed to remedy, and then he must supplement the written word so as to give "force and life" to the intention of the legislature. That was clearly laid down (3 Co. Rep. 7b) by the resolution of the judgdes (SIR ROGER MANWOOD, C.B., and the other barons of the Exchequer) in Heydon's case (4), and it is the safest guide to-day. Good practical advice on the subject was given about the same time by FLOWDEN in his note (2 Plowd. 465) to Eyston Vs. Studd (5). Put into homely metaphor it is this: A judge should ask himself the question how, if the makers of the Act had themselves come across this ruck in the texture of it, they would have straightened it out? He must then do as they would have done. A judge must not alter the material of which the Act is woven, but he can and should iron out the creases."

In **1980 (1) SCC 340** referred to supra the Supreme Court had held as hereunder:

> "(1) Parliament and the State Legislatures function best when they concern themselves with general principles, broad objectives and fundamental issues, instead of technical or situational intricacies which are better left to better equipped full time expert executive bodies and specialist public servants. Parliament and the State Legislatures have neither the time or expertise to be involved in detail or circumstance, nor can visualise and provide for new strange unforeseen or unpredictable situations. That is the raison d'etre for delegated legislation. The power to legislate carries with it the power to delegate. But excessive delegation may amount to abdication. Delegation unlimited may invite despotism uninihibited. So the theory has been evolved that the

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legislature cannot delegate its essential legislative function. Legislate it must, by laying down policy and principle and delegate it may to fill in detail and carry out policy. The legislature may guide the delegate by speaking through the express provision empowering delegation or the other provisions of the statute such as the preamble, the scheme or even the very subject-matter of the statute. If guidance there is, wherever it may be found, the delegation is valid. A good deal of latitude has been held to be permissible in the case of taxing statutes and on the same principle generous degree of latitude must be permissible in the case of welfare legislation, particularly those statutes which are designed to further the Directive Principles of State Policy."

In **1995 Supp. (1) SCC 235** referred to supra, the Supreme Court had held as hereunder:

"It is well settled that the legislative scheme may employ words of generality conveying its policy and intention to achieve the object set out therein. Every word need not be defined. It may be a matter of judicial construction of such words or phrases. Mere fact that a particular word or phrase has not been defined is not a ground to declare the provisions of the Act itself or the order as unconstitutional. The word "habitual" cannot be put in a straitjacket formula. It is a matter of judicial construction and always depends upon the given facts and circumstances in each case. As to when an inference that a tenant is habitually in arrears disentitling him to the protection of the Order could be drawn is a question of fact in each case. But on that ground or circumstance itself, the provision of the Act cannot be declared to be ultra vires."

The commentary on canons – interpretation of broad terms in Bennion – Statutory Interpretation contains the following passage:

"For the sake of brevity, or because the enactment has to deal with a multiplicity of circumstances, the draftsman often uses a broad term. This has the effect of delegating legislative power to the courts and officials who are called upon to apply the enactment. The governing legal maxim is generalia verba sunt generaliter intelligenda (general words are to be understood generally). {3 Co Inst 76.See Examples 78.5, 80.5 and 83.1} It is not to be supposed that the draftsman could have had in mind every possible combination of circumstances which may chance to fall within the literal meaning of general words. {For a detailed discussion of the concept of the broad term see Bennion Statute Law (2nd edn, 1983) Chap. 13}

The broad term which is a substantive has been called a nomen generale. {Hunter Vs. Bowyer (1850) 15 LTOS 281.} Other judicial descriptions of the broad term include 'open-ended

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expression' {Express Newspapers Ltd Vs. McShane [1980] 2 WLR 89, at p 94.}, 'word of the most loose and flexible description' {Green v Marsden (1853) 1 Drew 646.} and 'somewhat comprehensive and somewhat indeterminate term'. {Campbell v Adair [1945] JC 29.}

The broadest terms, such as 'reasonable' or 'just', virtually give the court or official an unlimited delegated authority, subject to the remedies available on judicial review or appeal. {As to these see s 24 of this Code (judicial review) and s 23 (appeal).}"

In **Girdhari Lal's case** referred to supra, the Supreme Court held as hereunder:

"Again, the words of a statute may not be designed to meet the several uncontemplated forensic situations that may arise. The draftsman may have designed his words to meet what Lord Simon of Glaisdale calls the "primary situation". It will then become necessary for the court to impute an intention to Parliament in regard to "secondary situations". Such "secondary intention" may be imputed in relation to a secondary situation so as to best serve the same purpose as the primary statutory intention does in relation to a primary situation."

Therefore it is clear from the case laws referred to above that Parliamentarians expresses its object and purpose in general terms when enacting a Statute and does not foresee the minute details that are likely to arise in the future and provide a solution for the same at the time when the Act itself is enacted. On the other hand, they would be acting wiser if they make only general expressions, leaving it to the experts / Statutory Authorities and then courts, to understand the general expressions used in the Statute in the context in which they are used in a case to case basis depending upon the facts available in each case. Using general expressions in a Statute, leaving the court to understand it's meaning, would not be a ground to declare a section or an Act ultra vires, is the law laid down by the Supreme Court in **Benilal's case** referred to supra. Interpretation of a Statute must be to advance the object which the Act wants to achieve.

15. Now, we went through the statements of objects and reasons of Amending Act 15/2005. As rightly emphasized by Mr.Soli Sorabji learned senior counsel for the petitioners, the statement of objects and reasons for Amending Act 15/2005 emphasises in more than one place that the amendment is in the discharge of India's obligation to "TRIPS", which forms part of the "WTO" agreement. Therefore a need has arisen for us to look into the relevant Articles of "TRIPS" for the limited purpose of what obligations are created under "TRIPS", which, India was attempting to discharge by bringing in Amending Act 15/2005. Article 7 of "TRIPS" **provides enough elbow room to a member country in complying with "TRIPS" obligations by bringing a law in a manner conducive to social and economic welfare and to a balance of rights and obligations**. Article 1 of "TRIPS" enables a member country free to determine the appropriate method of implementing the provisions of this agreement within their own legal

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system and practice. But however, any protection which a member country provides, which is more extensive in nature than is required under "TRIPS", shall not contravene "TRIPS". Article 27 speaks about patentability. Lengthy arguments have been advanced by learned Additional Solicitor General appearing for the Government of India, learned senior counsels and learned counsels appearing for the pharmaceutical companies that India, being a welfare and a developing country, which is pre-dominantly occupied by people below poverty line, it has a constitutional duty to provide good health care to it's citizens by giving them easy access to life saving drugs. In so doing, the Union of India would be right, it is argued, to take into account the various factual aspects prevailing in this big country and prevent evergreening by allowing generic medicine to be available in the market. As rightly contended by the learned Additional Solicitor General of India, the Parliamentary debates show that welfare of the people of the country was in the mind of the Parliamentarians when Ordinance 7/2004 was in the House. They also had in mind the International obligations of India arising under "TRIPS" and under "WTO" agreement. Therefore the validity of the amended section on the touchstone of Article 14 of the Constitution of India must be decided having regard to the object which Amending Act 15/2005 wanted to achieve.

16. It is argued by the learned senior counsels for the petitioners that since the amended section uses only general expressions, leaving it to the Statutory Authority to understand what it means, the Statutory Authority is likely to act arbitrarily in exercising it's discretion, since it has no guidelines. We have already held that the amended section cannot be said to be vague or ambiguous. We reiterate here at this stage that the amended section with it's Explanation is capable of being understood and worked out in a normal manner not only by the Patent applicant but also by the Patent controller. In other words, the patent controller would be guided by various relevant details which every patent applicant is expected to produce before him showing that the new discovery had resulted in the enhancement of the known efficacy; the derivatives differ significantly in properties with regard to efficacy and therefore it cannot be said that the patent controller had an uncanalised power to exercise, leading to arbitrariness. The argument that the amended section must be held to be bad in Law since for want of guidelines it gives scope to the Statutory Authority to exercise it's power arbitrarily, has to be necessarily rejected since, we find that there are in-built materials in the amended section and the Explanation itself, which would control / guide the discretion to be exercised by the Statutory Authority. In other words, the Statutory Authority would be definitely guided by the materials to be placed before it for arriving at a decision. Mr.P.S.Raman learned senior counsel brought to our notice two judgments of the Supreme Court reported in **AIR 1957 SC 397 (M/s.Pannalal Binjraj Vs. Union of India**) and **(1974) 1 SCC 549 (State of Punjab Vs. Khan Chand**) to highlight the types of discretions, if exercised, affecting various rights and the outcome of such exercise of discretion. We extract paragraph 34 of the judgment reported in **AIR 1957 SC 397** hereunder:

"34. There is a broad distinction between discretion which has to be exercised with regard to a fundamental right

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guaranteed by the Constitution and some other right whichis given by the statute. If the statute deals with a right which is not fundamental in character the statute can take it away but a fundamental right the statute cannot take away. Where for example, a discretion is given in the matter of issuing licences for carrying on trade, profession or business or where restrictions are imposed on freedom of speech etc., by the imposition of censorship, the discretion must be controlled by clear rules so as to come within the category of reasonable restrictions. Discretion of that nature must be differentiated from discretion in respect of matters not involving fundamental rights such as transfers of cases. As inconvenience resulting from a change of place or venue occurs when any case is transferred from one place to another but it is not open to a party to say that a fundamental right has been infringed by such transfer. In other words, the discretion vested has to be looked at from two points of view, viz., (1) does it admit of the possibility of any real and substantial discrimination, and (2) does it impinge on a fundamental right guaranteed by the Constitution? Article 14 can be invoked only when both these conditions are satisfied. Applying this test, it is clear that the discretion which is vested in the Commissioner of Income - Tax or the Central Board of Revenue, as the case may be, under s.5 (7-A) is not at all discriminatory."

From the above extracted portion, it is clear that Article 14 can be invoked only when it is shown that in the exercise of a discretionary power there is a possibility of a real and substantial discrimination and such exercise interferes with the fundamental right guaranteed by the Constitution. This judgment is by a Constitution Bench. The latter judgment [**(1974) 1 SCC 549**] is also by a Constitution Bench, which also quotes with approval the above extracted passage, in paragraph No.10 of that judgment. It is not shown by the learned senior counsels appearing for the petitioners before us that in the exercise of the discretionary power by the Patent controller, any of the petitioner's fundamental rights are violated namely, to carry on the trade or the petitioner stand singularly discriminated. We find that the amended section by itself does not discriminate nor does it prohibit the trade being carried on.

17. It is argued by the learned senior counsels for the petitioners that the Statutory Authority is likely to misuse the discretion vested in it by throwing out the patent application as **"not an invention"**, by relying upon the amended section, when the amended section itself does not contain any guidelines. We have already found that the amended section has in-built protection enabling each of the patent applicant to establish before the patent controller that his discovery had resulted in the enhancement of the known efficacy of that substance and the derivatives are significantly differing in properties with regard to efficacy. Therefore it boils down to only one question namely, could an arbitrary exercise of a discretionary power invalidate an Act? We have a direct answer to this point in favour of the State from a judgment of the Supreme Court reported in **2006 (8) SCC 212 (M.Nagaraj Vs. Union of India**),

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where, in paragraph No.106, the Supreme Court had held as hereunder:

> "Every discretionary power is not necessarily discriminatory. According to the Constitutional Law of India, by H.M.Seervai, 4th Edn., p.546, equality is not violated by mere conferment of discretionary power. It is violated by arbitrary exercise by those on whom it is conferred. This is the theory of "guided power". This theory is based on the assumption that in the event of arbitrary exercise by those on whom the power is conferred, would be corrected by the courts."

In the judgment reported in **2007-1-LW.Pg.724 (Selvi.J.Jayalalitha & Others Vs. The Union of India & Others**), rendered by one of us (Justice Prabha Sridevan), in dealing with such a contention namely, an Act must be invalidated because of possible misuse and abuse of the law, it was held as hereunder:

> "67. It was also contended that there could be flagrant misuse and abuse of the law. The possibility of flagrant abuse or misuse of law has never been a ground for holding a provision ultra vires. We cannot presume that the authorities will administer the law "with an evil eye and an unequal hand." This has been so held in several cases where the constitutionality of a legal provision was attacked. The observations of the Supreme Court in Krishna Lal's case (supra), where the Kerala Abkari Act was challenged, are squarely applicable to the present case. Merely because the Act requires the assessee to prove that there were circumstances which prevented the assessee from filing the return, it would not amount to violation of Article 20(3) of the Constitution."

We have already found that there is no ambiguity or vagueness in the expressions under attack as found incorporated in the amended section and the Explanation attached to it. Ultimately, in that case the conclusions were summed up by saying (See paragraph 75) that "no law can be declared illegal because there is a possibility of its misuse" and "the Legislature has a duty to safeguard the economic interest of the country." When the validity of any law touching upon the economic interests of a country comes up before court, what the court should do, had been stated by the Supreme Court in the judgment reproted in **(2006) 6 SCC 213 (Reiz Electrocontrols (P) Ltd. Vs. CCE**). In paragraph No.10 of that judgment, the Supreme Court had extracted paragraph No.10 of it's earlier judgment reported in **(1996) 3 SCC 407 (Union of India Vs. Paliwal Electricals (P) Ltd.**), wherein it was found stated as hereunder:

> "It is equally necessary to determine, as pointed out repeatedly by this court, that in economic and taxation spheres, large latitude should be allowed to the Legislature."

We could see that the Supreme Court, in **Paliwal's case** namely, **(1996) 3 SCC 407 had** taken in it's mind the observations made by a Constitution Bench of the Supreme Court in **R.K.Garg Vs. Union of India (1981) 4 SCC**

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675. In **R.K.Garg's case,** the following paragraph is found:

"Another rule of equal importance is that laws relating to economic activities should be viewed with greater latitude than laws touching civil rights such as freedom of speech, religion, etc. It has been said by no less a person than Holmes, J. that the legislature should be allowed some play in the joints, because it has to deal with complex problems which do not admit of solution through any doctrinaire or straitjacket formula and this is particularly true in case of legislation dealing with economic matters, where, having regard to the nature of the problems required to be dealt with, greater play in the joints has to be allowed to the legislature. The Court should feel more inclined to give judicial deference to legislative judgment in the field of economic regulation than in other areas where fundamental human rights are involved. Nowhere has this admonition been more felicitously expressed than in Morey Vs. Doud where Frankfurter, J. said in his inimitable style:

> "In the utilities, tax and economic regulation cases, there are good reasons for judicial self-restraint if not judicial deference to legislative judgment. The legislature after all has the affirmative responsibility. The courts have only the power to destroy, not to reconstruct. When these are added to the complexity of economic regulation, the uncertainty, the liability to error, the bewildering conflict of the experts, and the number of times the Judges have been overruled by events - self-limitation can be seen to be the path of judicial wisdom and institutional prestige and stability."

The court must always remember that "legislation is directed to practical problems, that the economic mechanism is highly sensitive and complex, that many problems are singular and contingent, that laws are not abstract propositions and do not relate to abstract units and are not to be measured by abstract symmetry" that exact wisdom and nice adaptation of remedy are not always possible and that "judgment is largely a prophecy based on meagre and uninterpreted experience". Every legislation particularly in economic matters is essentially empiric and it is based on experimentation or what one may call trial and error method and therefore it cannot provide for all possible situations or anticipate all possible abuses. There may be crudities and inequities in complicated experimental economic legislation but on that account alone it cannot be struct down as invalid. The courts cannot, as pointed out by the United States Supreme Court in Secretary of Agriculture Vs. Central Roig Refining Co. be converted into tribunals for relief from such crudities and inequities. There may even be possibilities of abuse, but that too cannot of itself be a ground for invalidating the legislation, because it is not possible for any legislature to anticipate as if by some divine

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prescience, distortions and abuses of its legislation which may be made by those subject to its provisions and to provide against such distortions and abuses. Indeed, howsoever great may be the care bestowed on its framing, it is difficult to conceive of a legislation which is not capable of being abused by perverted human ingenuity. The court must therefore adjudge the constitutionality of such legislation by the generality of its provisions and not by its crudities or inequities or by the possibilities of abuse come to light, the legislature can always step in and enact suitable amendatory legislation. That is the essence of pragmatic approach which must guide and inspire the legislature in dealing with complex economic issues."

In fact, we find that the above position in law is also spoken to by another Constitution Bench of the Supreme Court in the judgment reported in **2001 (4) SCC 139 (Union of India Vs. Elphinstone Spinning & Weaving Co. Ltd.) (See para 11**). It is a settled position in law **(See (2001) 4 SCC 139 - (at page 158**) that "it must be presumed that the Legislature understands and correctly appreciates the need of its own people, that its laws are directed to problems made manifest by experience and that its discriminations are based on adequate grounds." We now went through the Patents Act, 1970 as amended by Act 15/2005. In India there was an Act called Indians Patent & Designs Act enacted in the year 1911. The statement of objects and reasons of the Patents Act, 1970 (Act 39/1970) noticed that since the 1911 enactment, there had been substantial changes in the political and **economic conditions of the country** and therefore a need has arisen for a comprehensive law so as to ensure more effectively that patent rights are not worked out to the detriment of the consumer or to the prejudice of trade or the industrial development of the country, which was felt as early as 1948 resulting in the Government appointing the Patents Enquiry Committee to review the working of the Patents Law in India. Therefore right from the year 1948 or so, the Parliament was aware about the change in the economic conditions of the country, which made them to change the 1911 enactment to suit to the needs of the economic conditions of the country. Therefore there cannot be any doubt at all that the Patents Act as it stood then and as it stands today, is designed to safeguard the economic interests of this country and if that is so, the amended section must be viewed with greater latitude.

18. In **1996 (3) SCC 709 (State of A.P. Vs. Mc Dowell & Co.**) the Supreme Court reiterated the position that "a law made by Parliament or the Legislature can be struck down by courts on two grounds and two grounds alone namely, lack of legislative competence and violation of any of the fundamental rights guaranteed in Part III of the Constitution of India or of any other Constitutional provision." There is no third ground. In the case before us, learned senior counsels, except arguing that the amended section must be struck down on the ground of ambiguity, arbitrariness, leading to exercise of uncanalised powers – with which we have not agreed at all – had not shown any other legal ground to invalidate the amended section. In the same judgment, the Supreme Court had held as follows :

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"No enactment can be struck down by just saying that it is arbitrary or unreasonable. Some or other Constitutional infirmity has to be found before invalidating an Act. An enactment cannot be struck down on the ground that court thinks it unjustified. Parliament and the Legislatures, composed as they are of the representatives of the people, are supposed to know and be aware of the needs of the people and what is good and bad for them. The court cannot sit in judgment over their wisdom."

In **(2006) 3 SCC 434 (Bombay Dyeing & Mfg. Co.Ltd. (3) Vs. Bombay Environmental Action Group**) (See paragraph 205) it was held by the Supreme court that "arbitrariness on the part of the legislature so as to make the legislation violative of Article 14 of the Constitution should ordinarily be manifest arbitrariness. What would be arbitrary exercise of legislative power would depend upon the provisions of the statute vis-a-vis the purpose and object thereof". In AIR 1961 SC 1602 (Jyoti Pershad Vs. Union Territory of Delhi) the Supreme Court held as hereunder:

"So long as the Legislature indicates, in the operative provisions of the statute with certainty, the policy and purpose of the enactment, the mere fact that the legislation is skeletal, or the fact that a discretion is left to those entrusted with administering the law, affords no basis either for the contention that there has been an excessive delegation of legislative power as to amount to an abdication of its functions, or that the discretion vested is uncanalised and unguided as to amount to a carte blanche to discriminate. If the power or discretion has been conferred in a manner which is legal and constitutional, the fact that Parliament could possibly have made more detailed provisions, could obviously not be a ground for invalidating the law."

As we have already found, the amended section has in-built measures to guide the Statutory Authority in exercising it's power under the Act. We have also found that the amended section does not suffer from the vice of vagueness, ambiguity and arbitrariness. The Statutory Authority would be definitely guided in deciding whether a discovery is an invention or not by the materials to be placed before him by the Patent applicant. If that is so, then, going by the law laid down by the Supreme Court in M.Nagaraj's case referred to supra, if the Statutory Authority, in exercising his power, mis-directs himself; abuses his power in an arbitrary manner and passes an order, then, the same could be corrected by the hierarchy of forums provided in the Act itself in addition to the further reliefs available before the Courts of Law. When that is the position, then, we have to necessarily state that the amended section cannot be invalidated solely on the ground that there is a possibility of misusing the power.

19. Now we refer to the decisions mainly relied upon by the learned senior counsel for the petitioners. Mr.Soli Sorabji learned senior counsel relied upon the following judgments:

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(a) **AIR 1960 SC 554 (Hamdard Dawakhana & Anr. Vs. The Union**

of India & Others);

(b) **1961 Crl.L.J. 442 (The State of Madhya Pradesh & Anr. Vs. Baldeo Prasad**);

(c) **AIR 1970 SC 1453 (Harakchand Ratanchand Banthia & Others Vs. Union of India**); and

(d) **AIR 1967 SC 829 (Lala Hari Chand Sarda Vs. Mizo District Council and Another**).

We went through the judgments very carefully. In the first case, the Legislation impugned was stated to be in violation of Article 19 – restriction on freedom of speech – of the Constutiton of India. In considering the provisions of the Act challenged, the Supreme Court found that sections 3(d) and 8 of the Act are unconstitutional and arbitrary as they provided uncontrolled power to the executives to do the act. In the second case, the validity of Central Provinces and Berar Goondas Act, 1946 was in challenge. The Apex Court found various infirmities in the operative sections of the Act and upheld the order of the High court invalidating the offending provisions. In the third case, the validity of certain provisions of the Gold Control Act was in challenge. In the last case, there was a challenge to the validity of section 3 of the LUSHAI HILLS District (Trading by Non-Tribals) Regulation 2, 1963 was in challenge, being in violation of Article 19(1)(g) of the Act. In our respectful opinion, when the validity of an Act is challenged on the touchstone of Article 14 of the Constitution of India, the decision has to depend upon the provisions of the concerned Statute itself, which are in challenge. Of-course, law is well settled that when there is vagueness in any provision of law leading to arbitrary exercise of power / uncanalised powers, the Act should be struck down. Therefore whether any provision of law is hit by Article 14 of the Constitution of India on the ground stated above, would depend upon the construction of the provisions in challenge. When a particular Act is found to be suffering the vice of vagueness and arbitrariness, then, it must be held that it was so on the construction of that Statute. It cannot be said that whenever arbitrariness and vagueness are the vices projected as grounds of attack, the court should close it's eyes and simply strike down the law without even finding out whether in the Act challenged there are such vices. In fact, that is what the Supreme Court itself had said in the first judgment brought to our notice by Mr.Soli Sorabji learned senior counsel, which in turn quotes with approval an earlier judgment of the Supreme Court reported in **1954 SCR 674** wherein it is stated that "in order to decide whether a particular legislative measure contravenes any of the provisions of Part III of the Constitution of India, it is necessary to examine with some strictness the substance of the legislation in order to decide what the Legislature has really done." We again find in the first judgment that the Supeme Court had held as follows:

> "Another principle which has to be borne in mind in examining the Constitutionality of a Statute is that, it must be assumed that the Legislature understands and appreciates the need of the people and the laws it enacts are directed to problems which are made manifest by experience and that the elected representatives assembled in a Legislature enact laws which they consider to be reasonable for the purpose for which

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they are enacted. Presumption is therefore in favour of the Constitutionality of an enactment."

If we have the above referred to principles of law in mind on Statutory Interpretation, we have to state with great respect that the judgment of the Supreme Court brought to our notice by Mr.Soli Sorabji learned senior counsel, would not stand attracted to the case on hand. The validity of the provisions of law considered in those cases and the validity of the provision of law in contest before us are not in pari materia. There is definitely a difference in the language and wording of the provisions challenged in those cases and the one before us. The context in which the offending provisions are used in the Act in challenge is also totally different from the context in which the offending provisions in the cases decided by the Supreme Court are used. Of course, in those judgments, the Supreme Court had clearly laid down that vagueness / ambiguity and arbitrariness resulting in uncanalised powers are grounds to invalidate an Act. In other words, with great respect, we state that in all the cases brought to our notice by Mr.Soli Sorabji learned senior counsel, the Supreme Court, analysing the provisions of the Statute before them in the context of the arguments advanced, found that they are violative. We state that in this case we have already found, analysing the alleged offending provision, that it is not in violation of Article 14 of the Constitution of India. We have borne in mind the object which the Amending Act wanted to achieve namely, to prevent evergreening; to provide easy access to the citizens of this country to life saving drugs and to discharge their Constitutional obligation of providing good health care to it's citizens. We have also referred to the case laws brought to our notice by Mr.Habibullah Badsha viz., **(1974) 1 SCC Pg.549** (State of Punjab Vs. Khan Chand); **(1985) 1 SCC 234** (State of Maharashtra Vs. Kamal S. Durgule); **(1988) 2 SCC 415** (B.B.Rajwanshi Vs. State of U.P.); **(1989) 4 SCC 683** (A.N.Parasuraman Vs. State of Tamil Nadu); and **(2005) 12 SCC 77** (State of Rajasthan Vs. Basant Nahata). On a perusal of the same also, we are in a position to reiterate with respect that our conclusions based on the case laws brought to our notice by Mr.Soli Sorabji learned senior counsel would equally apply to the case laws brought to our notice by Mr.Habibullah Badsha learned senior counsel. For all the reasons stated above, on issue (c) we hold that the amended section is not in violation of Article 14 of the Constitution of India and accordingly, both the writ petitions are dismissed with no order as to costs.

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Sd/
Asst.Registrar

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Sub Asst.Registrar

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   Udyog Bhavan, New Delhi
2. The Controller General of Patents & Designs
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   G.S.T.Road, Guindy, Chennai - 600 032
+ 5 CCs to M/s.C.Daniel, Advocate SR NO 48654
+ 1 cc to Mr.A.A.Mohan, Advocate, SR No.48651
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